Average Sales Price (ASP) Reporting Requirements

Questions and Answers

General

Q1. Why do manufacturers have to report average sales prices to CMS?

A1. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) included several important provisions related to drug coverage and payment in the Medicare program. One of the provisions establishes a new Average Sales Price (ASP) payment system for the vast majority of Medicare Part B covered outpatient drugs and biologicals not paid on a cost or prospective payment system basis. The new payment system requires quarterly reporting of manufacturers' ASPs for these drugs. Types of drugs subject to the ASP reporting requirement include those furnished incident to a physician's service, those furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

Q2. Did CMS issue a regulation on the manufacturer submission of average sales price data?

A2. Yes. CMS issued the interim final rule titled "Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals." It was published on April 6, 2004 and is accessible on the CMS website at http://www.cms.hhs.gov/providers/drugs/default.asp.

Q3. How can the public submit comments regarding ASP submission interim final rule?

A3. Comments regarding the interim final rule on ASP submission may be sent to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1380-IFC, P.O. Box 8010, Baltimore, Maryland 21244-1850. Comments may also be submitted electronically to http://www.cms.hhs.gov/regulations/ecomments or to www.regulations.gov. Comments will be considered if we receive them at the appropriate address, as described above, no later than 5 p.m. on June 7, 2004.

Q4. If a manufacturer has questions on ASP reporting, how should they contact CMS?

A4. Manufacturers can submit questions to the e-mail mailbox: Sec303ASPdata@cms.hhs.gov, but submissions to the e-mail box will not be considered as comments on the April 6, 2004 rule.

Who Must Report

Q5. Who is required to submit ASP data?

A5. Drug manufacturers are required to submit ASP data. The term manufacturer means any entity engaged in the following:

- Production, preparation, propagation, compounding, conversion or processing of prescription drug product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
- Packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Please note that the term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in wholesaler activities are required to report ASP data for those drugs that they manufacture.

Q6. Will physicians, hospitals, PBMs, and HMOs be required to report ASP data to CMS?

A6. Only drug manufacturers as defined in section 1927(k)(5) of the Social Security Act are required to submit ASP data.

Q7. Are repackagers required to submit ASP data?

A7. Yes.

What Must Be Reported

Q8. For the purposes of the ASP calculation and reporting, is "unit" defined the same as under the Medicaid rebate program?

A8. "Unit" is not defined the same as in the Medicaid rebate program. For the purposes of the ASP calculation, ''unit'' is the product represented by the 11-digit NDC.

Q9. Do sales in the U.S. include sales in the commonwealth territories, trust territories, and protectorates?

A9. US sales do not include sales in the commonwealth territories, trust territories, and protectorates.

Q10. How can a manufacturer report the ASP of a drug if there are no sales of that drug?

A10. The ASP cannot be calculated if no units of the NDC are sold in that quarter. Manufacturers should report zero sales for the NDC.

Q11. How should manufacturers account for returned goods in the calculation of ASP?

A11. Manufacturers should subtract the value of the returns from the numerator of the ASP calculation and subtract the number of units returned from the denominator.

Q12. Should manufacturers include discounts given under the Medicare drug discount card program in their average sales price data submitted to CMS?

A12. No, as consistent with the MMA, manufacturers should exclude prices negotiated for covered discount card drugs under an endorsed discount card program in calculating ASP data. Beginning in 2006 when the Medicare Part D prescription drug benefit is implemented, manufacturers should also exclude any prices negotiated by a prescription drug plan (including a Medicare Advantage plan) or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) on behalf of Part D eligible individuals.

Q13. Can manufacturers exclude from ASP data submission all drug prices charged to disproportionate share hospitals?

A13. All sales to disproportionate share hospitals that participate in the 340B program should be excluded from the ASP calculation.

Q14. What are nominal sales?

A14. Nominal sales are defined as sales less than 10 percent of the Average Manufacturer's Price as calculated under the Medicaid Rebate Program agreements.

Q15. Should the manufacturer's ASP calculation be rounded to a specific decimal place?

A15. Yes. Carry to the 3rd decimal place and round the calculation to 2 decimal places.

Q16. Should administrative fees paid to buyers be included in the ASP calculation?

A16. Administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program and discounts under an endorsed discount card program, should be included in the calculation of ASP, if those sales are to an entity whose sales are included in the calculation of ASP and if they ultimately affect the price actually realized by the manufacturer.

Q17. Are zero and negative manufacturer ASP amounts possible?

A17. Yes, zero and negative manufacturer ASP amounts are possible.

Q18. Should the ASP calculations include sales of hemophilic drugs to home health care providers?

A18. Sales of hemophilic drugs to home health care providers should be included in the calculation of ASP.

Q19. Is a manufacturer required to report its wholesale acquisition cost each quarter?

A19. Section 1927(b)(3)(A) of the Act, as added by Section 303(i)(4)(B) of the MMA states that manufacturer's wholesale acquisition cost (WAC) is reported only if required by Medicare to make payment under section 1847A of the Social Security Act. There are two provisions under section 1847A that potentially

involve a Medicare payment based on the manufacturer's WAC. Thus, the manufacturer must report WAC in the following two circumstances:

(1) For a single source drug or biological, the payment under 1847A is the lesser of the ASP or the WAC. Manufacturers must report the WAC for a single source drug or biological if it is less than the ASP for a quarter.

(2) The payment methodology in cases where the average sales price during the first quarter of sales is unavailable is based on either the manufacturer's WAC or the Medicare payment methodologies in effect on November 1, 2003. Manufacturers should report WAC in cases where the average sales price during the first quarter of sales is unavailable.

Q20. Should manufacturers separately report information on those sales made at a nominal price each quarter?

A20. Information on sales made at a nominal price is an integral part of the manufacturer's ASP calculation. While manufacturers may choose to separately report information on those sales, we are not currently requiring this information to be separately reported from the ASP. As we gain more experience with the ASP system, we may require this information to be separately reported in the future.

Q21. Can manufacturers make assumptions with respect to a particular aspect of the ASP calculation in the absence of specific guidance in the Social Security Act or Federal regulations?

A21. In the absence of specific guidance in the Social Security Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the intent of the Social Security Act, Federal Regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.

How Must the Report Be Made

Q22. Is there a specific format that manufacturers have to use in order to submit their ASP to CMS?

A22. Yes. Manufacturers should report the ASP data to us in Microsoft® Excel, using the template provided in Addendum A of the interim final rule titled "Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals" that was published on April 6, 2004. It is accessible on the CMS website at http://www.cms.hhs.gov/providers/drugs/default.asp.

Q23. Will CMS accept paper submission of ASP data?

A23. The ASP data should be submitted electronically.

Q24. Can manufacturers submit ASP information to CMS via e-mail?
A24. We are exploring options for secure electronic transmission of the ASP information to CMS. At the present time, the data should not be e-mailed.

When Must the Report Be Filed

Q25. When does the first quarterly data submission have to be sent to CMS?
A25. The first quarterly submission must be submitted to CMS by April 30, 2004. Subsequent data must be submitted within 30 days after the end of each calendar quarter.

Q26. After CMS receives the ASP data, how soon will the information be incorporated into the pricing file?
A26. Timely and accurate data will be incorporated at the next available update. For example, the first quarter 2005 Medicare payment allowances will be based on the third quarter 2004 data submissions.

Where Must the Report Be Filed

Q27. Where should manufacturers submit their ASP data?
A27. When sending ASP data to CMS via first class mail, federal express mail, or overnight delivery, please use the following address:

Centers for Medicare & Medicaid Services
Hospital and Ambulatory Policy Group
Division of Ambulatory Services
ATTN: Marjorie D. Baldo (CMS-1380-IFC)
Mail Stop No. C4-01-06
7500 Security Boulevard
Baltimore, MD 21244
410-786-0548

Please include technical contact information for questions that may arise with the data submitted. Specifically, include the technical contact name, phone number, fax number, and e-mail address.

Manufacturers requiring acknowledgment of our receipt of their diskette or CD-ROM data must include a stamped, self-addressed postcard or envelope with their submission. This postcard or envelope will be date stamped and returned but will only acknowledge receipt of the diskette, or CD-ROM data. If the ASP information is unreadable, is in the wrong format, is blank or, in any other way cannot be processed by us (e.g., virus), a phone call to the technical contact will be made. Diskettes or CD-ROMs will NOT be returned under ANY circumstances.

Confidentiality

Q28. Will the ASP data submitted to CMS be releasable to the public?

A28. As indicated in Section 1927(b)(3)(D) of the Act, as amended by MMA section 303(i)(4)(D), information disclosed by the manufacturer in connection with the requirement for ASP data submission is confidential and, not withstanding other laws, shall not be disclosed by the Secretary (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as necessary by the Secretary to carry out the provisions of section 1847A or 1847B of the Act, and to permit the Inspector General of the Department of Health and Human Services, the Comptroller General, and the Director of the Congressional Budget Office to review the information provided.